



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,959	08/31/2001	Robert S. Osbakken	39187-1457	7962

24961 7590 07/24/2003

HELLER EHRMAN WHITE & MCAULIFFE LLP  
4350 LA JOLLA VILLAGE DRIVE  
7TH FLOOR  
SAN DIEGO, CA 92122-1246

EXAMINER

JAGOE, DONNA A

ART UNIT PAPER NUMBER

1614

DATE MAILED: 07/24/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/942,959

Applicant(s)

OSBAKKEN ET AL.

Examiner

Donna Jagoe

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 67-69 and 73-113 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-69 and 73-113 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: .

## **DETAILED ACTION**

***Claims 67-69 and 73-113 are presented for examination.***

### ***Specification***

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

### ***Claim Objections***

Claim 86 is objected to because of the following informalities: Claim 86 is objected to under 37 CFR 1.75 as being a duplicate of claim 80. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1614

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 67-69 and 73-113 rejected under 35 U.S.C. 103(a) as being unpatentable over Rubin et al. U.S. Patent No. 5,925,334 (AE) in view of Schmitt et al. U.S. Patent No. 4,950,477 (AA) and Saunders Manual of Medical Practice (U)

The claims are drawn to a method of treating sinusitis comprising nasally administering a pharmaceutical composition comprising betamethasone and a surfactant and optionally a second agent selected from the group consisting of an antihistamine, mast cell stabilizer, non-antibiotic anti-microbial agent, an anti-leukotriene, an anti-viral, antiseptic, a non-steroidal anti-inflammatory agent (NSAID), a combination of at least 2 antibiotics, an agent for treating nasal polyps, an anticholinergic agents and combinations thereof.

Rubin et al. teach surfactant such as DPPC and Exosurf ® mixed with an

Art Unit: 1614

aerosolizing agent to promote mucus clearance (see abstract, see column 4, lines 5-15, see claim 1). The use of the surfactant lowers the surface tension to enhance distribution and spreading of other medications to the lower respiratory tract such as surfactant and an antibiotic and a surfactant and an inhaled anti-inflammatory agent for conditions such as sinusitis (column 10, lines 10-34). Methods of administration of the surfactant composition include a metered dose inhaler, dry powder inhalation, jet nebulization and ultrasonic nebulization (column 9, lines 28-39).

Rubin does not teach particle size, the osmolality, pH or the NaCl equivalency of the composition.

Schmitt et al. teach administration of non-antimicrobial antibiotic such as amphotericin B by aerosol spray to prevent pulmonary infection (column 1, line 60 to column 2, line 4). The particle size of the polyene (amphotericin b) is from 0.5  $\mu\text{m}$  to 8.0  $\mu\text{m}$ . Schmitt et al. teach that the particle size is important because particles smaller than 0.5  $\mu\text{m}$  are exhaled and thus not retained in the lungs while particles greater than 8.0  $\mu\text{m}$  such as those produced in an atomizer do not reach the periphery of the lungs and therefore are not effective in preventing or treating the infection (column 2, lines 48-65).

Schmitt et al. is cited to teach a non-antimicrobial antibiotic and to provide motivation for the instantly claimed particle size. It does not teach treatment of sinusitis and it does not teach osmolality and NaCl equivalency.

Saunders Manual of Medical Practice teach that sinusitis is an inflammation of one or more paranasal sinuses but usually refers to infection of the sinuses (column 1,

Art Unit: 1614

page 90, 1<sup>st</sup> paragraph). Further, there may be an overlap between symptoms of acute or chronic sinusitis and other causes of nasal congestion such as allergic or viral rhinitis (column 1, page 90, 4<sup>th</sup> paragraph). Treatment includes antibiotics such as amoxicillin/clavulanate along with decongestants, mucolytics and other ciliator activators, nasal corticosteroids, antihistamines and saline (pages 91-92).

Saunders Manual is cited to teach the state of the art regarding treatment of sinusitis. It does not teach intra-nasal administration of the agents except the corticosteroids and it does not teach particle size, osmolality and NaCl equivalency of the composition.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the state of the art of the above references to combine the surfactants/antibiotics/anti-inflammatory agents of Rubin et al. with the non-antibiotic antimicrobial agent and particle size of Schmitt et al. and the other agents disclosed in Saunders Manual of Medical practice such as antibiotics, decongestants, mucolytics, nasal corticosteroids and antihistamines to treat sinusitis with the reasonable expectation of preparing formulations with multiple active agents which make the treatment more effective and potent. Furthermore, one of ordinary skill in the art would be motivated to optimize the osmotic pressure, pH and NaCl equivalency of the composition, by routine experimentation to include a wider range for different drugs.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

No claims are allowed.

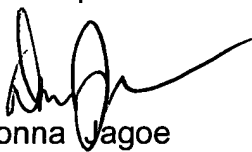
Art Unit: 1614

***Correspondence***

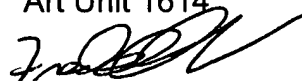
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Donna Jagoe  
Patent Examiner  
Art Unit 1614

Frederick Krass  
Primary Examiner  
Art Unit 1614



July 23, 2003